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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/017,660 | 12/12/2001 | Joseph S. Adorante | 2873 | 9669 |
| 26822 | 7590 | 03/22/2004 | EXAMINER | |
| WALTER A. HACKLER 2372 S.E. BRISTOL, SUITE B NEWPORT BEACH, CA 92660-0755 | | | FAY, ZOHREH A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/017,660 | ADORANTE, JOSEPH S. | |
| | Examiner | Art Unit | |
| | Zohreh Fay | 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 23-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Claims 23-26 are presented for examination.

The amendments and remarks filed on April 22, 2003 have been received and entered.

Claims 23-26 are again rejected under 35 U.S.C. 112 first paragraph for the reasons set forth on pages 2 and 3 of the office action of July 3, 2002 and the following reasons. Claims 23-26 are beyond the scope of the enabling disclosure as to the use of the term "preventing retinal ganglion cell death". The instant specification fails to provide guidance to a person skilled in the art to determine as to how the prevention is done. The state of the art also does not recognize that the prevention of conditions associated with retinal disorders is easily accomplished. (Ocular pharmacology, 4th Edition). The claims of the instant application are considered to be very broad, directed the prevention of any conditions rising from "retinal ganglion cell death". There are also no working examples to demonstrate the prevention of "retinal ganglion cell death". Therefore, there is a burden in terms of quantity of experimentation necessary for a person skilled in the art to determine the "prevention of retinal ganglion cell death".

Claims 23-26 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention is directed to a method of preventing retinal ganglion cell death administrating to the ganglion optic nerve of a mammal a pharmaceutical composition, which evokes a biological mechanism, which does not modulate aqueous humor dynamic and intraocular pressure. Such method

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requires the use of unspecified composition, and no evidence indicates that applicant knew such compositions. Therefore, the fact pattern indicates that artisan was not in possession of the claimed composition. The specification discloses examples of the structure of some compounds within the scope of what is claimed. However, there is no evidence that there is any per se structure/function relationship between the disclosed compounds and any other pharmaceutical compositions, which evokes biological mechanism, which does not modulate aqueous humor dynamics and intraocular pressure. Therefore, the claimed invention is not supported by adequate written description.

Claims 23-26 are rejected under 35 U.S.C. 102 (b) as being anticipated by Goldin et al. for the reasons set forth on Page 3 of the office action of January 29, 2003.

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant alleges criticality to the different use of the claimed invention in comparison to the prior art of record. The allegation is not well taken. The use of the claimed compounds for any reason in the body would inherently prevent the retinal ganglion cell death.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571)-272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (571) 272-0584. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Z.F
March 18, 2004

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Z.F.